Codman
a Johnson & Johnson company

K061568

SEP 29 2006

510(k) Summary

Submitter:
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, MA 02767-0350

Contact Person:
Jocelyn Raposo
Regulatory Affairs Specialist II
Phone Number: (508) 828-3421
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Date Prepared: June 2, 2006

Proprietary Name: CODMAN® EDS 3™ CSF External Drainage System
Common Name: External CSF Drainage System
Classification Name: Central nervous system fluid shunt and components

Predicate Device:
K902257 External Drainage System II
K910938 External Drainage System II
K954021 External Drainage System II

Device Description: The EDS 3 system is designed to collect cerebral spinal fluid (CSF) and other fluids of similar physical characteristics from a patient at a controlled rate based on differential pressure between the device and the patient. Collecting CSF from the patient is performed in efforts to reduce elevated intracranial pressure (ICP).

Intended Use: Use of the EDS 3 system is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

Performance Data: The fundamental scientific technology of EDS 3 is the same as EDS II. Bench testing was performed for the EDS 3 system. The modified device was deemed acceptable according to the acceptance criteria; therefore, the safety and efficacy of the product was not affected.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 29 2006

Codman & Shurtleff, Inc.
% Ms. Jocelyn Raposo
Regulatory Affairs Specialist II
325 Paramount Drive
Raynham, Massachusetts 02767-0350

Re: K061568
Trade/Device Name: Codman® 3™ CSF External Drainage System with/without Ventricular Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: August 30, 2006
Received: September 1, 2006

Dear Ms. Raposo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061568

Device Name: Codman® EDS 3™ CSF External Drainage System with/without Ventricular Catheter

Indications For Use:

Use of the CODMAN EDS 3 CSF External Drainage System is indicated for draining cerebrospinal fluid (CSF) and other fluids of similar physical characteristics as a means of reducing intracranial pressure and CSF volume when the insertion of a permanent, internal shunt is not indicated.

Prescription Use: _____X_____ OR Over-The-Counter Use:_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorat
and Neurological Devices

510(k) Number K061568/S1

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